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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/566,226	01/27/2006	Gilad Lavi	S2082/20003	3732
3000 7590 05/14/2007 CAESAR, RIVISE, BERNSTEIN, COHEN & POKOTILOW, LTD. 11TH FLOOR, SEVEN PENN CENTER 1635 MARKET STREET PHILADELPHIA, PA 19103-2212			EXAMINER SCHELL, LAURA C	
			ART UNIT 3767	PAPER NUMBER
			MAIL DATE 05/14/2007	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/566,226

Applicant(s)

LAVI ET AL.

Examiner

Laura C. Schell

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 27 January 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-18 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 9/13/06-10/31/06.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____.

DETAILED ACTION

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not identify the mailing address of each inventor. A mailing address is an address at which an inventor customarily receives his or her mail and may be either a home or business address. The mailing address should include the ZIP Code designation. The mailing address may be provided in an application data sheet or a supplemental oath or declaration. See 37 CFR 1.63(c) and 37 CFR 1.76.

It does not identify the city and either state or foreign country of residence of each inventor. The residence information may be provided on either an application data sheet or supplemental oath or declaration.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 12 and 17 and consequently dependent claims 2-11, 13-6 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 recites the limitation "the withdrawn position" in line 11. There is insufficient antecedent basis for this limitation in the claim.

Claim 12 recites the limitation "the driver sensor" in line 17. There is insufficient antecedent basis for this limitation in the claim.

Claim 17 recites the limitation "the needle shielded position" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen et al. (US Patent No. 6,319,233). Jansen discloses an injection device (Figs. 1-19) comprising: a housing (Fig. 2, 26) having a proximate end (near 38) and a distal end (near 12), the distal end having an opening therein (Fig. 3, 54); a cartridge barrel (Fig. 1, 16) within the housing, the cartridge barrel having proximate (near 24) and distal (near 18) ends; a needle cannula (18) fixed to the distal end of the cartridge barrel; a stopper (20) within the cartridge barrel; a driver (22) coupled to the stopper; a shield (28) coupled to the housing and slidable between a retracted and an extended position (Figs. 3 and 4); shield driver means (Fig. 4, 30) activateable to urge the shield from the retracted position to the extended position (Figs. 3 and 4); and sensor means (Fig. 5,

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sensor means are 32 and 66 (one element)) moveable with said driver (portions 66 and 32 move together as they are one element; Portions 66 and 32 move with the driver when the driver contacts portion 66 and moves 66 down to 44. Please note that Applicant has not claimed at what points the sensor moves with the driver or for what duration/length) and in slidable contact with an exterior surface of said cartridge barrel or an interior surface of said housing (Fig. 5 discloses that portions 66 and 32 are in slidable contact with both the exterior surface of the cartridge barrel and the interior surface of the housing (64)), the sensor means arranged to detect an end profile of the barrel or housing and to trigger activation of the shield driver means upon detection (the sensor means (66 and 32) detect an end profile of the barrel through the stopper's detection of the end of the barrel as seen in Fig. 4, and this triggers the sensor means to activate the shield driver means (30) upon detection. Please note that Applicant's claim language is very broad as to how the sensor means detects the end profile of the barrel or housing, and is broad enough to includes the examiner's interpretation).

In reference to claim 2, Jansen discloses that the shield driver means comprises a coil spring (30) within which the cartridge barrel is located (Figs. 3 and 4 disclose that the spring surrounds the cartridge barrel).

In reference to claim 3, Jansen discloses that the shield driver means comprises a release mechanism for fixing the spring relative to the driver in a compressed state (Fig. 3), the release mechanism being actuatable by said sensor means to release the spring (Fig. 3 and 4).

In reference to claim 4, Jansen discloses that the driver is arranged to be manually pushed through the housing, the driver carrying the shield driver means to a shield activation point (Figs. 3 and 4, 48).

In reference to claim 5, Jansen discloses that the coil spring is fixed at its proximal end to the driver, and the spring release mechanism fixes the spring to the driver at the distal end (Fig. 3).

In reference to claim 6, Jansen discloses that the shield driver means additionally provides a driving force for said driver (Fig. 4).

In reference to claim 7, Jansen discloses that the coil spring is fixed at its proximal end to the housing, and the spring release mechanism fixes the spring to the driver at its distal end (Fig. 3).

In reference to claim 8, Jansen discloses that the sensor means comprises one or more deformable arms attached or formed integrally with the driver (Fig. 5).

In reference to claim 9, Jansen discloses that each arm is biased against the exterior surface of the cartridge barrel and arranged to follow the surface profile of the barrel (Fig. 3-5).

In reference to claim 10, Jansen discloses that the release mechanism comprises a catch provided on a radially outer surface of each deformable arm (Fig. 3-5).

In reference to claim 11, Jansen discloses that the driver and the sensor means are a single molded plastic element (Figs. 3 and 5).

Claims 12-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Jansen et al. (US Patent No. 6,319,233). Jansen discloses a cartridge barrel (Fig. 1, 16), said barrel arranged to contain a stopper (20) and fluid therein and wherein said barrel has a second open end (near 24) and a second end (near 24) having a radial flange (24) adjacent to the second end; a needle cannula (18) having a sharp distal end and a second open end (closest to 16), the fluid being in communication with said needle second end; a housing (26) surrounding said barrel (Figs. 3 and 4), said housing having a distal open end (54) adjacent the needle and a proximate end (near 38) having a flange (38) receiving the radial flange of the barrel; a shield (28) releasably retained by the housing, said housing and said shield arranged in a sliding relationship with the shield positioned primarily within the housing until release (Fig. 3 and 4); a driver (22), said driver positioned partially within said housing (Fig. 3 discloses that 2 is surrounded by the housing and therefore partially within the housing), said driver equipped with at least one deformable side arm sensing the end of the barrel (side arm is the arm/flange portion at the end opposite 20. this arm senses the end of the barrel as shown in Fig. 5, as the arm contacts 24 when 20 reaches the end of the barrel), said driver slidably located within said housing for moving the stopper forward (Fig. 3 and 4); and a biasing spring (30), said biasing spring further adapted to bias the shield to cover the needle after the driver sensor detects the end of the barrel (Fig. 4 discloses the spring biasing the shield to cover the needle. Fig. 5 discloses that once the stopper hits the end of the barrel and is sensed by the contact between the arm and 24, then the spring is released as shown in Fig. 4).

In reference to claim 13, Jansen discloses that the biasing spring is carried by the driver and is released to bias the shield when the end of the barrel is reached (Figs. 3 and 4).

In reference to claim 14, Jansen discloses that the driver has two sensor elements (two sides of the arm flange portion opposite 20) to detect the end of the barrel.

In reference to claim 15, Jansen discloses that the housing and shield are equipped with latches (48, 58).

In reference to claim 16, Jansen discloses that the latches prevent premature release of the shield (Fig. 3 and 5).

In reference to claim 17, Jansen discloses that the latches retain the shield in the needle shield position (Figs. 3 and 5).

In reference to claim 18, Jansen discloses that the driver is deformable during assembly (Fig. 1).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura C. Schell whose telephone number is (571) 272-7881. The examiner can normally be reached on Monday-Friday 9am-5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

